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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/072,272
Filing Date: February 06, 2002
Appellant(s): STRONG ET AL.

Ms. Leslie A. Robinson
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5/26/2009 appealing from the Office action mailed 6/11/2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of the claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

The following is a listing of the evidence (e.g., patents, publications, Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

TAP Report 1 ("Photodynamic Therapy of Subfoveal Choroidal Neovascularization in Age-related Macular Degeneration with Verteporfin." Arch Ophtalmol. 1999; 117:1329-1345) (the TAP Report)

Zeimer (US Patent 5,935,942)

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 5-12, 14-18, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over TAP Report 1 ("Photodynamic Therapy of Subfoveal Choroidal Neovascularization in Age-related Macular Degeneration with Verteporfin." Arch Ophtalmol. 1999; 117:1329-1345) (the TAP Report).

The instant claims are directed to methods of treating an occult choroidal neovascular (CNV) lesion comprising administering photodynamic therapy to a subject having Occult CNV, wherein the subject is assessed as having either or both (a) a small lesion with a size less than about 4-5 disc areas or (b) poor visual acuity of less than about 65 letters prior to treatment and wherein the occult lesion comprise an occult component of >50% to <100% of the lesion.

The TAP Report teaches the instantly claimed method. Tap Report teaches methods of administering verteporfin, a green porphyrin (which is also known as BPD-MA, see Reg Number 129497-78-5) to patients suffering from Occult CNV. (see page 1330 under the heading Patient Selection, last para.). Out of the 402 Patients in the Vertoporfin arm of the study, at least 305 patients had evidence of Occult CNV (see Table 2 at page 1334, last criteria under the category Evidence of Occult CNV). Further, out of the same 402 patients at least 199 patients had a visual acuity of less than 53 letters (see Table 2, Vertoporfin Arm, under the category Visual Acuity criteria). Thus, at least about 100 patients who had received a photodynamic regimen of verteporfin, had evidence of Occult CNV with visual acuity of less than 65.

Further, Table 5 shows benefit from verteporfin therapy on patients with ≥50% classic CNV (or ≤50% occult CNV). Furthermore, the upper limit of the claimed invention (99% occult CNV) is also obvious because of the teaching that "the subgroup with no classic CNV (100% occult CNV) had a large treatment benefit" from pg. 1339 of the TAP Report.

Examiner also states that among the population in the Verteporfin Arm, 259 appear to have lesion size of less than 6 disc areas (see page 1335, table 2, under Vertoporfin Arm, Under the Area of Lesion, MPS Disc Areas criteria). Therefore, the population who showed Occult CNV in the TAP Report and further received verteporfin, are the same as the instantly claimed population. Said population received an aqueous Verteprofin solution in amount of about 6 mg/m^2 (see abstract, also page 1332, at 1st col). Fifteen minutes after administration of the Verteprofin the CNV lesions were irradiated with a laser light for about 83 seconds in a light exposure of 50 J/cm^2. (see col 1 page 1332). Accordingly, the limitations of claims 14-18 are met.

All method steps of the instantly claimed process are described for the population who showed Occult CNV prior to the therapy in the TAP Report Verteporfin Arm. Accordingly, the instantly claimed intended purpose is inherently achieved in the said population.

Applicant is also informed that the recitation of 45% efficacy of therapy in Occult CNV group, as recited in page 1338 is not a teaching away, because such conclusion does not mean that no patient has benefited from the methodology described in Vertopoifin Arm of the TAP Report. Rather, such percentage is only viewed as a comparison to the control group. Examiner adds that the 33.1% of the TAP Report's Verteporfin Arm included lesion. TAP Report only fails to explicitly state that the patients in the Verteporfin Arm of the study had an occult component of >50% to <100% of the lesion.

Nevertheless, absent a showing of unexpected results or evidence to the contrary, it would have been obvious to one of ordinary skill in the art at the time of invention to practice the method steps of TAP Report to treat patients with occult CNV lesion having an occult component of >50% to <100% of the lesion, because as shown by the Report, one of ordinary skill in the art would have had a reasonable expectation of success to observe some degree of improvement in ocular condition of the patients suffering from said occult CNV.

Claims 13 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over the TAP Report as applied to claims 1-2, 5-12, 14-18, 20 in view of Zeimer (US Patent 5,935,942).

The teachings of the TAP report are described above. The TAP report only fails to specifically describe attachment the use of a targeting ligand and the dosing of its photosensitizer per body weight of subjects.

Zeimer is used to describe the same process as in TAP report except that the photosensitizer is encapsulated or coupled with a targeting or tissue specific agent (see col 12, lines 28-50; col 14, lines 15-col 24). The process of Zeimer employs targeted liposomes (col 25-26) for patients having Occult CNV.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to add a targeting agent, such as an antibody, to the photosensitizer employed in TAP report, because as suggested by Zeimer, the ordinary skill in the art would have had a reasonable expectation of success in improving the clinical outcome.

Further, absent a showing of criticality, it would have been obvious to one of ordinary skill in the art at the time of invention to optimize the dosing ranges of the photosensitizer in TAP report by routine experimentation and express it based on the body weight of subjects.

(10) Response to Argument

Appellant argues against Examiner's interpretation of the Tap Report 1, particularly the claimed subgroup being inherently located in the verteporfin-treatment population. Appellant respectfully submit that because certain patients having poor visual acuity and/or small lesion size also have some evidence of occult CNV does not necessarily mean that such patients fell within the scope of the claims. Moreover, the Examiner's conclusions ignores the express teachings of the Tap Report 1 that occult lesions, and particularly lesions having between >50% and <100% occult character, are non-responsive to PDT treatment with verteporfin. Appellant points to where the TAP Report explicitly teaches that patients with greater than 50% to less than 100% occult CNV achieved no benefit from verteporfin PDT therapy. Appellant points to Table 5 (pg. 1340) in the Tap Report 1, where there was no significant differential between verteporfin-treated patients and placebo-treatment group. Appellant point to the author's conclusion that "no appreciable difference was observed in the group of patients with lesions in which the area of classic CNV was greater than 0% but less than 50% of the area of the entire lesion at baseline." Finally, Appellant argues that the secondary reference, Zeimer, does not remedy the deficiencies of the Tap Report 1 as stated above.

This is not persuasive because the results that there was no benefit from verteporfin therapy in Table 5 only refers to the subset of patients with >0 to <50% classic CNV (or >50 to <100% occult CNV). However, there is no denying the large benefit of verteporfin in the subset of patients with ≥50% of classic CNV (or ≤50% occult CNV) as disclosed also in Table 5. So, the data can infer that a patient with 50% occult CNV benefits from verteporfin therapy. Therefore, it would be obvious to administer verteporfin therapy to a patient with 51% occult CNV due to routine experimentation and optimization. Furthermore, the upper limit of the claimed invention (99% occult CNV) is also obvious because of the teaching that "the subgroup with no classic CNV (100% occult CNV) had a large treatment benefit" from pg. 1339 of the TAP Report.

Appellant is reminded that the standard for obviousness is not absolute but a reasonable expectation of success. In this manner, it is obvious to experiment with a subgroup of patients on the outer limits of the claimed range of ≥50 to ≤100% occult CNV. Therefore, absent a teaching of unexpected results or the criticality of the claimed range, it is obvious over the cited prior art.

Appellant claims unexpected and advantageous improvement in visual acuity in a sub-population of occult CNV patients having small lesion size or poor visual acuity prior to treatment, with an enhanced improvement in visual acuity for occult CNV patients having both of these additional characteristics.

This is not persuasive because it is the Examiner's position that Appellant has not established a case of unexpected results when compared to the cited prior art and that is commensurate with the scope of the claims. The data pointed to in Appellant's

specification (43.8% difference between the verteporfin and placebo groups) is not a clear and convincing case of unexpected results.

Regarding the establishment of unexpected results or synergism, a few notable principles are well settled. The Appellant has the initial burden to explain any proffered data and establish how any results therein should be taken to be unexpected and significant. See MPEP 716.02 (b). It is Appellant's burden to present clear and convincing factual evidence of nonobviousness or unexpected results, i.e., side-by-side comparison with the closest prior art in support of nonobviousness for the instant claimed invention over the prior art. The claims must be commensurate in the scope with any evidence of unexpected results. See MPEP 716.02 (d). With regard to synergism, a prima facie case of synergism has not been established if the data or result is not obvious. The synergism should be sufficient to overcome the obviousness, but must also be commensurate with the scope of the claims. Further, if the Appellant provides a DECLARATION UNDER 37 CFR 1.132, it must compare the claimed subject matter with the closest prior art in order to be effective to rebut a prima facie case if obviousness. See MPEP 716.02 (e).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Yong S. Chong/

Yong S. Chong
Primary Examiner
Art Unit 1617

August 3, 2009

Conferees:

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